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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,003	07/12/2005	Rainer Sturmer	12810-00113-US	4124

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CONNOLLY BOVE LODGE & HUTZ, LLP  
P O BOX 2207  
WILMINGTON, DE 19899

EXAMINER
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CHENG, KAREN

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,003	<b>Applicant(s)</b> STURMER, RAINER	
	<b>Examiner</b> Karen Cheng	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/16/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 6-8 are currently pending in the instant application.

#### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement filed on 03/16/07 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

#### ***Response to Amendment and Arguments***

Applicant's amendments and arguments filed on 03/16/07 have been fully considered and entered into the application. Applicants' amendments have overcome the following rejections:

- The 35 USC 112 2nd paragraph rejections of claims 6 and 9 have been overcome by the amendment to the claims that delete the trademark term "Duloxetine" and cancellation of claim 9.
- The 35 USC 103(a) rejection of claim 9 has been overcome in view of applicant's cancellation of claim 9.

Applicants' arguments in regards to the 35 USC 103(a) rejections have been considered but are not found persuasive. Applicant argues that the claimed process is directed towards preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)propylamine oxalate and that applicant's claimed process requires reacting thiophene with 3-chloropropionic acid chloride and subsequently with methylamine. Applicant argues that since the prior art of Deeter *et al* does not teach reacting thiophene with 3-chloropropionic acid chloride and subsequently with methylamine to form 3-methylamino-1-(2-thienyl)-1-propanone, the process as claimed should be

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considered novel. Applicant is reminded that the process being claimed is the preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)propylamine oxalate from 3-methylamino-1-(2-thienyl)-1-propanone and that this process has been taught by Deeter *et al* (see previous and maintained 35 USC 103(a) rejection). Applicant is reminded that preparation of 3-methylamino-1-(2-thienyl)-1-propanone through a distinct process does not render the product, 3-methylamino-1-(2-thienyl)-1-propanone, as novel. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113. Nor does it change the actual process that is claimed, which is the preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)propylamine oxalate from 3-methylamino-1-(2-thienyl)-1-propanone. The claimed process is still the synthesis of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)propylamine from 3-methylamino-1-(2-thienyl)-1-propanone, a process has been taught in the prior art by Deeter *et al*. Therefore the 35 USC 103(a) rejections of claims 6 and 7 in view of Deeter *et al* are maintained.

***Maintained Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeter *et al*, Tetrahedron Letters, **31**, 1990.

Applicants instant elected invention in claims 6 and 7 teach preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate or an acid addition salt thereof through the reduction of 3-methylamino-1-(2-thienyl)-1-propanone, or an acid addition salt thereof to (1S)-3-methylamino-1-(2-thienyl)propan-1-ol, or an acid addition salt thereof.

Determination of the scope and content of the prior art (MPEP §2141.01)

Deeter *et al*. teach the preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate through the intermediate 3-(dimethylamino)-1-(2-thienyl)-1-propanone, which is reduced to (1S)-3-(dimethylamino)-1-(2-thienyl)propan-1-ol, transformed into (+)-(S)-N-dimethyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate, and dealkylated to give the desired product (See Deeter *et al*, p. 7102).

*Ascertainment of the different between the prior art and the claims (MPEP §2141.02)*

The difference between the prior art of Deeter *et al* and the instantly claimed processes of 6 and 7 is that Deeter *et al* inventions are directed to reduction and subsequent reaction of tertiary amine compounds rather than the secondary amine compounds claimed in the instant invention.

*Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)*

Deeter *et al* is analogous art because the compounds found in the art possess similar activity. In Ex part Bluestone, 135 USPQ 199, secondary and tertiary amines are stated to be interchangeable. In the absence of unexpected results, one skilled in the art would expect that the instant claims which are analogous to Deeter *et al* compounds, i.e. secondary amine vs tertiary amine, is prima facie. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In the instant case, the preparation of the secondary amine would be desirable since the compound of interest, duloxetine, contains a secondary amine. The explicit teaching of Deeter *et al* together with the enabled examples would have motivated one skilled in the art to modify the known compounds with such generic teaching with the expectation that they would all have similar activity as taught by Deeter *et al*.

***Maintained Claim Objections***

Claim 8 is objected to as being dependent upon a rejected base claim, but would appear allowable over the prior art of record if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

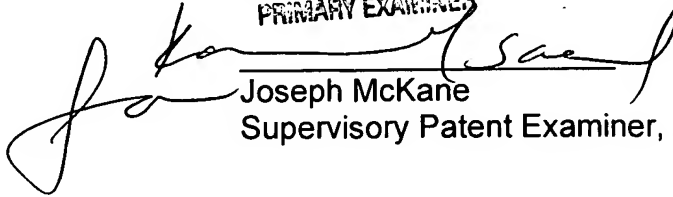
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Karen Cheng  
Patent Examiner, AU 1626

KAMALA SAGED, PH.D.  
PRIMARY EXAMINER



Joseph McKane  
Supervisory Patent Examiner, AU 1626